Remarks/Arguments:

Favorable reconsideration of the above-identified patent application, in light of the above amendments and the following remarks is respectfully requested. The presently pending claims are claims 1-3, 5-7. Claims 1 and 3 have been amended. Claim 4 has been canceled. Claim 7 has been added.

In paragraphs 1 and 2 of the Office Action, the Examiner stated that claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,446,288 to Pi (Pi). The Examiner stated that Pi discloses a method of reducing an amount of positive air pressure that attending personnel must maintain in a supine obese individual's lungs to move the individual's diaphragm. The Examiner also stated that the position of the patient's head, neck and shoulders relative to the patient's middle and lower torso would inherently (due to gravity) cause any patient's abdominal mass to fall away form the diaphragm.

In response, the Applicant has amended independent claims 1 to better differentiate Applicant's invention from the cited references. Pi discloses a medical support pillow which merely supports the head and neck of the patient. Pi recommends positioning an *ordinary* individual's head above a support surface with the purpose of linearly aligning an individual's mouth, pharynx, and trachea. Pi merely discloses positioning the upper back, rather than positioning the entire lower and upper back (thoracic spine). The Applicant's invention teaches supporting an ***obese individual's head at a height to linearly align the individual's mouth, pharynx, trachea***, while permitting the easy movement of the individual's diaphragm If one skilled in the art simply scaled the invention

of Pi to achieve the present invention's height, an enlarged support device would be created that would negate Pi's intended purpose. Although obese individuals by definition have larger bodies than normal people, their heads are not correspondingly larger than normal. The enlarged head cavity of a scaled up version of Pi's invention would no longer fit the obese individual's head. Without proper positioning of the head, neck, chest, and abdomen , the obese individual's mouth, pharynx, and trachea would be difficult to align and the enlarged version of Pi's invention would be non-functional. In addition, Pi never addresses the problems associated with properly positioning an ***obese*** person. Since Pi, merely discloses the use of devices for normal sized persons rather than solving the problems inherent with obese people, Pi does not disclose raising the shoulders and entire back at an angle sufficient to move the diaphragm of an obese person.

The Examiner stated that in the method disclosed in Pi, a patient's head and neck are raised at an angle (22-40 degrees) relative to a base surface for the purpose of facilitating endotracheal intubation. The Examiner also stated that the position of the patient's head, neck and shoulders relative to the patient's middle and lower torso would inherently (due to gravity) cause an obese patient's abdominal mass to fall away from the diaphragm. However, the Applicant completely disagrees. In Pi, merely the head and an upper-most position of the shoulders are raised, but not sufficiently to cause the abdominal mass of an obese person to fall away from the diaphragm. On the other hand, the Applicant's claim invention raises the entire back and shoulders at the sufficient angle to allow the abdominal mass of the obese person to fall away from the diaphragm.

In regards to inherency, inherency may be relied upon where, but only where, the consequence of following the reference disclosure always inherently produces or results in the claimed invention. *W.L. Gore Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Circ. 1983). If there is not a reasonable certainty that the claimed subject matter will necessarily result, the rejection fails. Also, accidental results, not intended and not appreciated, do not constitute an anticipation. *Georgia-Pacific Corp. v. United States Plywood Corp.*, 118 U.S.P.Q. 122, 128 (2nd Circ. 1958). Therefore, the withdrawal of the rejection and the allowance of claim 1 is respectfully requested.

In paragraphs 3 and 4, the Examiner rejected claim 2 under 35 U.S.C. 103(a) as being unpatentable over Pi in view of U.S. Patent No. 4,918,774 to Popitz (Popitz). The Examiner stated that Pi does not disclose a head and neck support approximately six inches in height above the base structure. However, the Examiners stated that Popitz teaches supporting an individual's head and neck on a head and neck support approximately six inches in height above the base surface.

In response, the Applicant has amended independent claims 1 to better differentiate Applicant's invention from the cited references. Claim 2 depends from amended independent claim 1 and recite additional limitations in combination with the novel elements of claim 1.

Popitz describes a support device which merely elevates the head and upper shoulders. Popitz does disclose the use of a support device to align an individual's oropharyngeal, laryngeal, and tracheal axes, but merely for a normal sized person. However, the Applicant's invention is intended to be used with obese individuals for which Pi or Popitz would not be useable. Unlike

Popitz and Pi, the Applicant's invention raises the entire back. The elevation of an individual's upper body (to include the entire back) and corresponding relationship of the head, neck and lumbar area are critical to achieving the alignment of the oral, pharyngeal, and laryngeal axes and causing the individual's abdominal mass to fall away from the diaphragm, thereby reducing the amount of force required to move the individual's diaphragm. Thus, neither Pi nor Popitz teaches or suggests raising the entire back and shoulders at the angle sufficient to move the obese individual's diaphragm. Therefore, the withdrawal of the rejection and the allowance of claim 2 is respectfully requested. In paragraph 5, the Examiner rejected claim 3 under 35 U.S.C. 103(a) as being unpatentable over Pi in view of U.S. Patent No. 5,682,632 to Cotroneo (Cotroneo). The Examiner stated that Pi does not teach anesthetizing the patient and ventilating the patient. The Examiner also stated that Cotroneo teaches anesthetizing the patient and ventilating the patient for the purpose of placing a patient in a state which is conducive to a medical operation and for the purpose of maintaining a patient's airway during an emergency situation, respectively. The Examiner stated that it would have been obvious to modify Pi to includes the steps of anesthetizing and ventilating a patient because it would have placed a patient in a state which is conducive to a medical operation and maintained a patient's airway during an emergency as taught by Cotroneo.

In response, the Applicant has amended independent claims 3 to better differentiate Applicant's invention from the cited references. Neither Pi nor Cotroneo teaches or suggests elevating the entire back and shoulders at an angle sufficient to cause the abdominal mass of an obese individual to fall away from the diaphragm. The Applicant's invention provides a method

which elevates **the entire back**, and not merely the head, neck and shoulders, at a sufficient angle to cause the abdominal mass to fall away. Therefore, the withdrawal of the rejection and the allowance of claim 3 is respectfully requested.

In paragraph 6, the Examiner rejected claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over Pi in view of Cotroneo as applied to claim 3 above and further in view of Popitz. The Examiner stated that the difference between Pi as modified by Cotroneo and claim 4 is raising the patient's head and neck approximately six inches above the base surface. The Examiner stated that Popitz teaches supporting an individual's head and neck on a head and neck support approximately six inches in height above the base surface for the purpose of automatically aligning the airway axes thereby opening the airways of the individual and facilitating the intubation of the individual. The Examiner also stated that it would have been obvious to further modify the height of the head and neck support of Pi to make it approximately six inches because it would have provide a means for automatically aligning the airway axes thereby opening the airways of the individual and facilitating the intubation of the individual as taught by Popitz.

In response, the Applicant has amended independent claims 3 to better differentiate Applicant's invention from the cited references. Claim 4 has been canceled. Claims 5 and 6 depend from amended independent claim 3 and recite additional limitations in combination with the novel elements of claim 3. As stated above, Pi does not disclose raising the entire back and shoulders sufficiently to cause the abdominal mass to fall away from the diaphragm. Rather, Pi merely discloses raising the shoulders and a small portion of the upper back, which would not be sufficient

to move the abdominal mass away from the obese person's diaphragm. Therefore, the withdrawal of the rejection and the allowance of claims 5 and 6 is respectfully requested.

The prior art references illustrates an existing knowledge of back, neck, and head support in various means to linearly align the mouth, pharynx, and trachea. Typically, in a normally sized individual, the prior art supports were sufficient to align the individual's axes, thus aiding the individual's breathing efforts. Indeed, the prior art support devices do not recognize nor teach the need to also ease an individual's breathing efforts by supporting the individual's back, neck, and head at a sufficient height to cause the individual's abdominal mass to fall away from the individual's diaphragm. As noted in the Applicant's specification, the population has been slowly shifting to a higher percentage of obese individuals with problems inherent to a larger shaped human body. The prior art supports are inadequate in disclosing or providing a motivation to assisting an obese individual's breathing.

Applicant has submitted Exhibit 1–an appended medical reference dated June 2003 to illustrate the current state of the art in dealing with obese individuals. ***Prior art references were obviously not utilized because none of the prior art references sufficiently solves the problems with obese individuals.*** The morbidly obese patient (a patient whose body weight exceeds twice the patient's recommended weight) is precariously perched upon a pile of towels and blankets to achieve the recommended body position for tracheal intubation, i.e. elevating/isolating the patient's upper airway (mouth/throat) above the patient's chest. Exhibit 1 compared the results of the elevated technique to prior art techniques of elevating the "patient's heads only 8 cm prior to laryngoscopy"

(a height comparable to prior art pillows): laryngoscopy was more successful and less complicated for a sufficiently elevated obese individual. Elevating a patient is not an obvious technique. Rather, Exhibit 1 illustrates the fact that elevating a patient is a new technique, although the method of stacking pillows is dangerous and not effective.

The technique espoused in Exhibit 1 to deal with obese individuals has some problems. A patient so positioned is prone to shifting. Attending personnel may have to spend excessive amounts of time piling the towels and blankets. The recommended pile or stack of blankets, positions an obese patient's head far from the end of the support surface. To "reach" or work with the patient's airway, the attending personnel are required to lean excessively over the obese patient. This creates an awkward/uncomfortable position for the attending anesthesia personnel. Consequently, many attending personnel choose not to practice this elevating technique due to these inherent problems. Thus the need for a stable, simple, elevating device to improve airway management for obese patients–a need for the present invention.

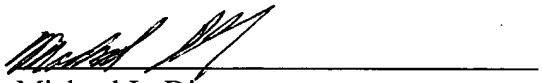
The Applicant respectfully maintains that this invention is novel and non-obvious. The prior art lacks suggestion nor teaches the Applicant's invention. An obvious rejection should not be applied using present knowledge of an invention in retrospect. The prior art did not recognize the need to elevate and thus "dimension" a support device to a sufficient height facilitating the easy movement of an individual's abdominal mass. The mere fact a prior art structure could be modified to produce the claimed invention, does not render the modification obvious to one skilled in the art

unless the prior art suggested the desirability of the modification. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Circ. 1992); *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

CONCLUSION

For all the above reasons, the Applicant respectfully requests the reconsideration and withdrawal of the rejection and the allowance of claims 1-3 and 5-7.

Respectfully submitted,



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LETTERS TO THE EDITOR

Anesthetic Considerations for Bariatric Surgery: Proper Positioning is Important for Laryngoscopy

Jay B. Brodsky, MD, Harry J. M. Lemmens, MD, John G. Brock-Utne, MD, Lawrence J. Saidman, MD, and Richard Levitan, MD

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To the Editor:

Although we appreciate the reference to our study on tracheal intubation in morbidly obese patients (1), the recent comprehensive review of anesthetic considerations for bariatric surgery by Ogunnaike et al. misses a key point (2).

One of the most important criterion for insuring successful direct laryngoscopy and tracheal intubation in this population is patient position. The recommendation that the shoulders and head be elevated so the tip of the chin is *just* higher than the chest may not maximize the view during laryngoscopy (2,3). It is essential that the morbidly obese patient be placed with the head, upper body, and shoulders significantly elevated above the chest. One of the authors (RL), has described an easily visible parameter, that is, an imaginary *horizontal* line should connect the patient's sternal notch with the external auditory meatus (Fig. 1).

View larger version (136K):

Figure 1. A morbidly obese patient will be in position for direct laryngoscopy when an imaginary horizontal line can be drawn from the sternal notch to the external auditory meatus. To achieve this, the upper body and head should be significantly elevated with pillows, blankets, or towels. Reproduced from Airway Cam Video Series, Volume 3: Advanced Airway Imaging and Laryngoscopy Techniques, published by Airway Cam Technologies, Inc., Wayne, PA. Used by permission.

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With our patients in this position, we successfully intubated the tracheas of 99 of 100 morbidly obese patients by direct laryngoscopy (1). In the same issue of *Anesthesia & Analgesia*, Keller et al. reported a 97% success rate with direct laryngoscopy in obese and morbidly obese patients (4). Although successful tracheal intubation was similar in both studies, there were 9 patients (15%) who required a bougie, and in only 20 patients (33%) was a Cormack Grade I view (5) present in the Keller study. In contrast, none of our patients required a bougie, and 75% had a Cormack Grade I view during laryngoscopy. Keller et al. elevated their patients' heads only 8 cm prior to laryngoscopy (4).

We believe it is essential that morbidly obese patients be positioned correctly in order to maximize the view during direct laryngoscopy for tracheal intubation.

References

1. Brodsky JB, Lemmens HJM, Brock-Utne JG, et al. Morbid obesity and tracheal intubation. Anesth Analg 2002; 94: 732 6.[Abstract/Free Full Text]
2. Ogunnaike BO, Jones SB, Jones DB, et al. Anesthetic considerations for bariatric surgery. Anesth Analg 2002; 95: 1793 805.[Free Full Text]
3. McCarroll SM, Saunders PR, Brass PJ. Anesthetic considerations in obese patients. Prog Anesthesiol 1989; 3: 1 12.
4. Keller C, Brimacombe J, Kleinsasser A, Brimacombe L. The Laryngeal Mask Airway™ as a temporary ventilatory device in grossly and morbidly obese patients before laryngoscope-guided tracheal intubation. Anesth Analg 2002; 94: 737 40.[Abstract/Free Full Text]
5. Cormack RS, Lehane J. Difficult tracheal intubation in obstetrics. Anaesthesia 1984; 39: 1105 11. [ISI][Medline]

Response

Babatunde O. Ogunnaike, MD, Stephanie B. Jones, MD, Charles W. Whitten, MD, Daniel B. Jones, MD, and David Provost, MD

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In Response:

We appreciate the comments of Brodsky et al. regarding our recent review article on anesthetic considerations for bariatric surgery (1), with particular emphasis on the issue of positioning for successful direct laryngoscopy and tracheal intubation in morbidly obese patients.

While it may be true that merely elevating the head and shoulders so that the tip of the chin is just higher

than the chest may not maximize the laryngoscopic view for endotracheal intubation, we mentioned this fact because of documentation that this positioning is better than maintaining a totally flat position during laryngoscopy (2,3). However, we did not specifically mention how much higher than the chest the tip of the chin should be elevated, and the words "just higher" were certainly not implied in our review article.

We appreciate your providing information about an easily visible parameter to facilitate laryngoscopy in the morbidly obese as described by one of your authors, in which an imaginary horizontal line to connect the patient's sternal notch with the external auditory meatus is used as a landmark to facilitate laryngoscopy. We have also observed that the higher the elevation of the head and chest, the easier laryngoscopy and intubation become in the morbidly obese patient. Thank you for the letter.

References

1. Ogunnaike BO, Jones SB, Jones DB, et al. Anesthetic considerations for bariatric surgery. Anesth Analg 2002; 95: 1793 805.[Free Full Text]
2. Ogunnaike BO, Whitten CW. Anesthetic management of morbidly obese patients. Semin Anesth 2002; 21: 46 58.
3. Keller C, Brimacombe J, Kleinsasser A, Brimacombe L. The Laryngeal Mask Airway™ as a temporary ventilatory device in grossly obese patients before laryngoscope-guided tracheal intubation. Anesth Analg 2002; 94: 737 40.[Abstract/Free Full Text]